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To establish the Food Safety Administration to protect the public health by preventing food-borne illness, ensuring the safety of food, improving research on contaminants leading to food-borne illness, and improving security of food from intentional contamination, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 6, 2005

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To establish the Food Safety Administration to protect the public health by preventing food-borne illness, ensuring the safety of food, improving research on contaminants leading to food-borne illness, and improving security of food from intentional contamination, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Safe Food Act of 2005”.

- 1 (b) TABLE OF CONTENTS.—The table of contents of
 2 this Act is as follows:

Sec. 1. Short title; table of contents.
 Sec. 2. Findings; purposes.
 Sec. 3. Definitions.

TITLE I—ESTABLISHMENT OF FOOD SAFETY ADMINISTRATION

Sec. 101. Establishment of Food Safety Administration.
 Sec. 102. Consolidation of separate food safety and inspection services and agencies.
 Sec. 103. Additional duties of the Administration.

TITLE II—ADMINISTRATION OF FOOD SAFETY PROGRAM

Sec. 201. Administration of national program.
 Sec. 202. Registration of food establishments and foreign food establishments.
 Sec. 203. Preventative process controls to reduce adulteration of food.
 Sec. 204. Performance standards for contaminants in food.
 Sec. 205. Inspections of food establishments.
 Sec. 206. Food production facilities.
 Sec. 207. Federal and State cooperation.
 Sec. 208. Imports.
 Sec. 209. Resource plan.
 Sec. 210. Traceback.

TITLE III—RESEARCH AND EDUCATION

Sec. 301. Public health assessment system.
 Sec. 302. Public education and advisory system.
 Sec. 303. Research.

TITLE IV—ENFORCEMENT

Sec. 401. Prohibited Acts.
 Sec. 402. Food detention, seizure, and condemnation.
 Sec. 403. Notification and recall.
 Sec. 404. Injunction proceedings.
 Sec. 405. Civil and criminal penalties.
 Sec. 406. Presumption.
 Sec. 407. Whistleblower protection.
 Sec. 408. Administration and enforcement.
 Sec. 409. Citizen civil actions.

TITLE V—IMPLEMENTATION

Sec. 501. Definition.
 Sec. 502. Reorganization plan.
 Sec. 503. Transitional authorities.
 Sec. 504. Savings provisions.
 Sec. 505. Conforming amendments.
 Sec. 506. Additional technical and conforming amendments.
 Sec. 507. Regulations.
 Sec. 508. Authorization of appropriations.

Sec. 509. Limitation on authorization of appropriations.

Sec. 510. Effective date.

1 **SEC. 2. FINDINGS; PURPOSES.**

2 (a) FINDINGS.—Congress finds that—

3 (1) the safety of the food supply of the United
4 States is vital to the public health, to public con-
5 fidence in the food supply, and to the success of the
6 food sector of the Nation's economy;

7 (2) lapses in the protection of the food supply
8 and loss of public confidence in food safety are dam-
9 aging to consumers and the food industry, and place
10 a burden on interstate commerce;

11 (3) the safety and security of the food supply
12 requires an integrated, system-wide approach to pre-
13 venting food-borne illness, a thorough and broad-
14 based approach to basic and applied research, and
15 intensive, effective, and efficient management of the
16 Nation's food safety program;

17 (4) the task of preserving the safety of the food
18 supply of the United States faces tremendous pres-
19 sures with regard to—

20 (A) emerging pathogens and other con-
21 taminants and the ability to detect all forms of
22 contamination;

23 (B) an aging and immune compromised
24 population, with a growing number of people at

1 high-risk for food-borne illnesses, including in-
2 fants and children;

3 (C) an increasing volume of imported food,
4 without adequate monitoring and inspection;
5 and

6 (D) maintenance of rigorous inspection of
7 the domestic food processing and food service
8 industries;

9 (5) Federal food safety standard setting, in-
10 spection, enforcement, and research efforts should be
11 based on the best available science and public health
12 considerations and food safety resources should be
13 systematically deployed in ways that most effectively
14 prevent food-borne illness;

15 (6) the Federal food safety system is frag-
16 mented, with at least 12 Federal agencies sharing
17 responsibility for food safety, and operates under
18 laws that do not reflect current conditions in the
19 food system or current scientific knowledge about
20 the cause and prevention of food-borne illness;

21 (7) the fragmented Federal food safety system
22 and outdated laws preclude an integrated, system-
23 wide approach to preventing food-borne illness, to
24 the effective and efficient operation of the Nation's

1 food safety program, and to the most beneficial de-
2 ployment of food safety resources;

3 (8) the National Academy of Sciences rec-
4 ommended in the report “Ensuring Safe Food from
5 Production to Consumption” that Congress establish
6 by statute a unified and central framework for man-
7 aging Federal food safety programs, and rec-
8 ommended modifying Federal statutes so that in-
9 spection, enforcement, and research efforts are
10 based on scientifically supportable assessments of
11 risks to public health; and

12 (9) the lack of a single focal point for food safe-
13 ty leadership in the United States undercuts the
14 ability of the United States to exert food safety lead-
15 ership internationally, which is detrimental to the
16 public health and the international trade interests of
17 the United States.

18 (b) PURPOSES.—The purposes of this Act are—

19 (1) to establish a single agency to be known as
20 the “Food Safety Administration” to—

21 (A) regulate food safety and labeling to
22 strengthen the protection of the public health;

23 (B) ensure that food establishments fulfill
24 their responsibility to produce food in a manner

1 that protects the public health of all people in
2 the United States;

3 (C) lead an integrated, system-wide ap-
4 proach to food safety and to make more effec-
5 tive and efficient use of resources to prevent
6 food-borne illness;

7 (D) provide a single focal point for food
8 safety leadership, both nationally and inter-
9 nationally; and

10 (E) provide an integrated food safety re-
11 search capability, utilizing internally-generated,
12 scientifically and statistically valid studies, in
13 cooperation with academic institutions and
14 other scientific entities of the Federal and State
15 governments, to achieve the continuous im-
16 provement of research on food-borne illness and
17 contaminants;

18 (2) to transfer to the Food Safety Administra-
19 tion the food safety, labeling, inspection, and en-
20 forcement functions that, as of the day before the ef-
21 fective date of this Act, are performed by other Fed-
22 eral agencies; and

23 (3) to modernize and strengthen the Federal
24 food safety laws to achieve more effective application

1 and efficient management of the laws for the protec-
2 tion and improvement of public health.

3 **SEC. 3. DEFINITIONS.**

4 In this Act:

5 (1) ADMINISTRATION.—The term “Administra-
6 tion” means the Food Safety Administration estab-
7 lished under section 101(a)(1).

8 (2) ADMINISTRATOR.—The term “Adminis-
9 trator” means the Administrator of Food Safety ap-
10 pointed under section 101(a)(3).

11 (3) ADULTERATED.—

12 (A) IN GENERAL.—The term “adulter-
13 ated” has the meaning described in subsections
14 (a) through (c) of section 402 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C.
16 342).

17 (B) INCLUSION.—The term “adulterated”
18 includes bearing or containing a contaminant
19 that causes illness or death among sensitive
20 populations.

21 (4) AGENCY.—The term “agency” has the
22 meaning given that term in section 551 of title 5,
23 United States Code.

1 (5) CATEGORY 1 FOOD ESTABLISHMENT.—The
2 term “category 1 food establishment” means a food
3 establishment that slaughters animals for food.

4 (6) CATEGORY 2 FOOD ESTABLISHMENT.—The
5 term “category 2 food establishment” means a food
6 establishment that processes raw meat, poultry, sea-
7 food products, regardless of whether the establish-
8 ment also has a kill step, and animal feed and other
9 products that the Administrator determines by regu-
10 lation to be at high risk of contamination and the
11 processes of which do not include a step validated to
12 destroy contaminants.

13 (7) CATEGORY 3 FOOD ESTABLISHMENT.—The
14 term “category 3 food establishment” means a food
15 establishment that processes meat, poultry, seafood
16 products, and other products that the Administrator
17 determines by regulation to be at high risk of con-
18 tamination and whose processes include a step vali-
19 dated to destroy contaminants.

20 (8) CATEGORY 4 FOOD ESTABLISHMENT.—The
21 term “category 4 food establishment” means a food
22 establishment that processes all other categories of
23 food products not described in paragraphs (5)
24 through (7).

1 (9) CATEGORY 5 FOOD ESTABLISHMENT.—The
2 term “category 5 food establishment” means a food
3 establishment that stores, holds, or transports food
4 products prior to delivery for retail sale.

5 (10) CONTAMINANT.—The term “contaminant”
6 includes a bacterium, chemical, natural or manufac-
7 tured toxin, virus, parasite, prion, physical hazard,
8 or other human pathogen that when found on or in
9 food can cause human illness, injury, or death.

10 (11) CONTAMINATION.—The term “contamina-
11 tion” refers to a presence of a contaminant in food.

12 (12) FOOD.—

13 (A) IN GENERAL.—The term “food”
14 means a product intended to be used for food
15 or drink for a human or an animal.

16 (B) INCLUSIONS.—The term “food” in-
17 cludes any product (including a meat food prod-
18 uct, as defined in section 1(j) of the Federal
19 Meat Inspection Act (21 U.S.C. 601(j))), capa-
20 ble for use as human food that is made in whole
21 or in part from any animal, including cattle,
22 sheep, swine, or goat, or poultry (as defined in
23 section 4 of the Poultry Products Inspection
24 Act (21 U.S.C. 453)), and animal feed.

1 (C) EXCLUSION.—The term “food” does
2 not include dietary supplements, as defined in
3 section 201(ff) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 321(ff)).

5 (13) FOOD ESTABLISHMENT.—

6 (A) IN GENERAL.—The term “food estab-
7 lishment” means a slaughterhouse, factory,
8 warehouse, or facility owned or operated by a
9 person located in any State that processes food
10 or a facility that holds, stores, or transports
11 food or food ingredients.

12 (B) EXCLUSIONS.—For the purposes of
13 registration, the term “food establishment”
14 does not include a farm, restaurant, other retail
15 food establishment, nonprofit food establish-
16 ment in which food is prepared for or served di-
17 rectly to the consumer, or fishing vessel (other
18 than a fishing vessel engaged in processing, as
19 that term is defined in section 123.3 of title 21,
20 Code of Federal Regulations).

21 (14) FOOD PRODUCTION FACILITY.—The term
22 “food production facility” means any farm, ranch,
23 orchard, vineyard, aquaculture facility, or confined
24 animal-feeding operation.

1 (15) FOOD SAFETY LAW.—The term “food safe-
2 ty law” means—

3 (A) the provisions of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 301 et
5 seq.) related to and requiring the safety, label-
6 ing, and inspection of food, infant formulas,
7 food additives, pesticide residues, and other
8 substances present in food under that Act;

9 (B) the provisions of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 301 et
11 seq.) and of any other Act that are adminis-
12 tered by the Center for Veterinary Medicine of
13 the Food and Drug Administration;

14 (C) the Poultry Products Inspection Act
15 (21 U.S.C. 451 et seq.);

16 (D) the Federal Meat Inspection Act (21
17 U.S.C. 601 et seq.);

18 (E) the Egg Products Inspection Act (21
19 U.S.C. 1031 et seq.);

20 (F) the Sanitary Food Transportation Act
21 of 1990 (49 U.S.C. App. 2801 et seq.);

22 (G) the provisions of the Humane Methods
23 of Slaughter Act of 1978 (Public Law 95–448)
24 administered by the Food Safety and Inspection
25 Service;

1 (H) the provisions of this Act; and

2 (I) such other provisions of law related to
3 and requiring food safety, labeling, inspection,
4 and enforcement as the President designates by
5 Executive order as appropriate to include within
6 the jurisdiction of the Administration.

7 (16) FOREIGN FOOD ESTABLISHMENT.—The
8 term “foreign food establishment” means a slaugh-
9 terhouse, factory, warehouse, or facility located out-
10 side the United States that processes food for con-
11 sumption that is imported into the United States or
12 food ingredients.

13 (17) INTERSTATE COMMERCE.—The term
14 “interstate commerce” has the meaning given that
15 term in section 201(b) of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 321(b)).

17 (18) MISBRANDED.—The term “misbranded”
18 has the meaning given that term in section 403 of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 343).

21 (19) PROCESS.—The term “process” or “proc-
22 essing” means the commercial harvesting, slaughter,
23 packing, preparation, or manufacture of food.

24 (20) SAFE.—The term “safe” refers to human
25 and animal health.

1 (21) STATE.—The term “State” means—

2 (A) a State;

3 (B) the District of Columbia;

4 (C) the Commonwealth of Puerto Rico;

5 and

6 (D) any other territory or possession of the

7 United States.

8 (22) VALIDATION.—The term “validation”

9 means the obtaining of evidence that the food hy-

10 giene control measure or measures selected to con-

11 trol a hazard in food is capable of effectively and

12 consistently controlling the hazard.

13 (23) STATISTICALLY VALID.—With respect to a

14 study, the term “statistically valid” means evaluated

15 and conducted under standards set by the National

16 Institute of Standards and Technology.

17 **TITLE I—ESTABLISHMENT OF**
 18 **FOOD SAFETY ADMINISTRATION**

19 **SEC. 101. ESTABLISHMENT OF FOOD SAFETY ADMINISTRA-**
 20 **TION.**

21 (a) ESTABLISHMENT.—

22 (1) IN GENERAL.—There is established in the

23 executive branch an agency to be known as the

24 “Food Safety Administration”.

1 (2) STATUS.—The Administration shall be an
2 independent establishment (as defined in section 104
3 of title 5, United States Code).

4 (3) HEAD OF ADMINISTRATION.—The Adminis-
5 tration shall be headed by the Administrator of Food
6 Safety, who shall be appointed by the President, by
7 and with the advice and consent of the Senate.

8 (b) DUTIES OF ADMINISTRATOR.—The Adminis-
9 trator shall—

10 (1) administer and enforce the food safety law;

11 (2) serve as a representative to international
12 food safety bodies and discussions;

13 (3) promulgate regulations to ensure the secu-
14 rity of the food supply from all forms of contamina-
15 tion, including intentional contamination; and

16 (4) oversee—

17 (A) implementation of Federal food safety
18 inspection, enforcement, and research efforts, to
19 protect the public health;

20 (B) development of consistent and science-
21 based standards for safe food;

22 (C) coordination and prioritization of food
23 safety research and education programs with
24 other Federal agencies;

1 (D) prioritization of Federal food safety ef-
 2 forts and deployment of Federal food safety re-
 3 sources to achieve the greatest possible benefit
 4 in reducing food-borne illness;

5 (E) coordination of the Federal response to
 6 food-borne illness outbreaks with other Federal
 7 and State agencies; and

8 (F) integration of Federal food safety ac-
 9 tivities with State and local agencies.

10 **SEC. 102. CONSOLIDATION OF SEPARATE FOOD SAFETY**
 11 **AND INSPECTION SERVICES AND AGENCIES.**

12 (a) TRANSFER OF FUNCTIONS.—For each Federal
 13 agency specified in subsection (b), there are transferred
 14 to the Administration all functions that the head of the
 15 Federal agency exercised on the day before the effective
 16 date of this Act (including all related functions of any offi-
 17 cer or employee of the Federal agency) that relate to ad-
 18 ministration or enforcement of the food safety law, as de-
 19 termined by the President.

20 (b) TRANSFERRED AGENCIES.—The Federal agen-
 21 cies referred to in subsection (a) are—

22 (1) the Food Safety and Inspection Service of
 23 the Department of Agriculture;

24 (2) the Center for Food Safety and Applied Nu-
 25 trition of the Food and Drug Administration;

1 (3) the part of the Agriculture Marketing Serv-
2 ice that administers shell egg surveillance services
3 established under the Egg Products Inspection Act
4 (21 U.S.C. 1031 et seq.);

5 (4) the resources and facilities of the Office of
6 Regulatory Affairs of the Food and Drug Adminis-
7 tration that administer and conduct inspections of
8 food establishments and imports;

9 (5) the resources and facilities of the Office of
10 the Commissioner of the Food and Drug Adminis-
11 tration that support—

12 (A) the Center for Food Safety and Ap-
13 plied Nutrition;

14 (B) the Center for Veterinary Medicine;
15 and

16 (C) the Office of Regulatory Affairs facili-
17 ties and resources described in paragraph (4);

18 (6) the Center for Veterinary Medicine of the
19 Food and Drug Administration;

20 (7) the resources and facilities of the Environ-
21 mental Protection Agency that control and regulate
22 pesticide residues in food;

23 (8) the part of the Research, Education, and
24 Economics mission area of the Department of Agri-

1 culture related to food safety and animal feed re-
2 search;

3 (9) the part of the National Marine Fisheries
4 Service of the National Oceanic and Atmospheric
5 Administration of the Department of Commerce that
6 administers the seafood inspection program;

7 (10) the Animal and Plant Inspection Health
8 Service of the Department of Agriculture; and

9 (11) such other offices, services, or agencies as
10 the President designates by Executive order to carry
11 out this Act.

12 **SEC. 103. ADDITIONAL DUTIES OF THE ADMINISTRATION.**

13 (a) OFFICERS AND EMPLOYEES.—The Administrator
14 may—

15 (1) appoint officers and employees for the Ad-
16 ministration in accordance with the provisions of
17 title 5, United States Code, relating to appointment
18 in the competitive service; and

19 (2) fix the compensation of those officers and
20 employees in accordance with chapter 51 and with
21 subchapter III of chapter 53 of that title, relating to
22 classification and General Schedule pay rates.

23 (b) EXPERTS AND CONSULTANTS.—The Adminis-
24 trator may—

1 (1) procure the services of temporary or inter-
2 mittent experts and consultants as authorized by
3 section 3109 of title 5, United States Code; and

4 (2) pay in connection with those services the
5 travel expenses of the experts and consultants, in-
6 cluding transportation and per diem in lieu of sub-
7 sistence while away from the homes or regular
8 places of business of the individuals, as authorized
9 by section 5703 of that title.

10 (c) BUREAUS, OFFICES, AND DIVISIONS.—The Ad-
11 ministrators may establish within the Administration such
12 bureaus, offices, and divisions as the Administrator deter-
13 mines are necessary to perform the duties of the Adminis-
14 trator.

15 (d) ADVISORY COMMITTEES.—

16 (1) IN GENERAL.—The Administrator shall es-
17 tablish advisory committees that consist of rep-
18 resentatives of scientific expert bodies, academics,
19 industry specialists, and consumers.

20 (2) DUTIES.—The duties of an advisory com-
21 mittee established under paragraph (1) may include
22 developing recommendations with respect to the de-
23 velopment of new processes, research, communica-
24 tions, performance standards, and inspection.

1 **TITLE II—ADMINISTRATION OF**
2 **FOOD SAFETY PROGRAM**

3 **SEC. 201. ADMINISTRATION OF NATIONAL PROGRAM.**

4 (a) IN GENERAL.—The Administrator shall—

5 (1) administer a national food safety program
6 (referred to in this section as the “program”) to
7 protect public health; and

8 (2) ensure that persons who produce or process
9 food meet their responsibility to prevent or minimize
10 food safety hazards related to their products.

11 (b) COMPREHENSIVE ANALYSIS.—The program shall
12 be based on a comprehensive analysis of the hazards asso-
13 ciated with different food and with the processing of dif-
14 ferent food, including the identification and evaluation
15 of—

16 (1) the severity of the potential health risks;

17 (2) the sources and specific points of potential
18 contamination extending from the farm or ranch to
19 the consumer that may render food unsafe;

20 (3) the potential for persistence, multiplication,
21 or concentration of naturally occurring or added
22 contaminants in food;

23 (4) opportunities across the food production,
24 processing, distribution, and retail system to reduce
25 potential health risks; and

1 (5) opportunities for intentional contamination.

2 (c) PROGRAM ELEMENTS.—In carrying out the pro-
3 gram, the Administrator shall—

4 (1) adopt and implement a national system for
5 the registration of food establishments and foreign
6 food establishments and regular unannounced in-
7 spection of food establishments;

8 (2) enforce the adoption of process controls in
9 food establishments, based on best available sci-
10 entific and public health considerations and best
11 available technologies;

12 (3) establish and enforce science-based stand-
13 ards for—

14 (A) substances that may contaminate food;
15 and

16 (B) safety and sanitation in the processing
17 and handling of food;

18 (4) implement a statistically valid sampling pro-
19 gram to ensure that industry programs and proce-
20 dures that prevent food contamination are effective
21 on an ongoing basis and that food meets the stand-
22 ards established under this Act;

23 (5) implement procedures and requirements to
24 ensure the safety and security of imported food;

1 (6) coordinate with other agencies and State or
2 local governments in carrying out inspection, en-
3 forcement, research, and monitoring;

4 (7) have access to the surveillance data of the
5 Centers for Disease Control and Prevention, and
6 other Federal Government agencies, in order to im-
7 plement a national surveillance system to assess the
8 health risks associated with the human consumption
9 of food or to create surveillance data and studies;

10 (8) develop public education risk communica-
11 tion and advisory programs;

12 (9) implement a basic and applied research pro-
13 gram to further the purposes of this Act; and

14 (10) coordinate and prioritize food safety re-
15 search and educational programs with other agen-
16 cies, including State or local agencies.

17 **SEC. 202. REGISTRATION OF FOOD ESTABLISHMENTS AND**
18 **FOREIGN FOOD ESTABLISHMENTS.**

19 (a) IN GENERAL.—The Administrator shall by regu-
20 lation require that any food establishment or foreign food
21 establishment engaged in processing food in the United
22 States be registered with the Administrator.

23 (b) REGISTRATION REQUIREMENTS.—

24 (1) IN GENERAL.—To be registered under sub-
25 section (a)—

1 (A) in the case of a food establishment, the
2 owner, operator, or agent in charge of the food
3 establishment shall submit a registration to the
4 Administrator; and

5 (B) in the case of a foreign food establish-
6 ment, the owner, operator, or agent in charge
7 of the foreign food establishment shall—

8 (i) submit a registration to the Ad-
9 ministrator; and

10 (ii) provide the name, address, and
11 emergency contact information of the
12 United States agent for the foreign food
13 establishment.

14 (2) REGISTRATION.—A food establishment or
15 foreign food establishment shall submit a registra-
16 tion under paragraph (1) to the Administrator
17 that—

18 (A) identifies the name, address, and emer-
19 gency contact information of each food estab-
20 lishment or foreign food establishment that the
21 registrant operates under this Act and all trade
22 names under which the registrant conducts
23 business relating to food;

24 (B) lists the primary purpose and business
25 activity of each food establishment or foreign

1 food establishment, including the dates of oper-
2 ation if the food establishment or foreign food
3 establishment is seasonal;

4 (C) lists the types of food processed or sold
5 at each food establishment or, for foreign food
6 establishments selling food for consumption in
7 the United States, identifies the specific food
8 categories of that food as listed under section
9 170.3 of title 21, Code of Federal Regulations;
10 and

11 (D) not later than 30 days after a change
12 in the products, function, or legal status of the
13 food establishment or foreign food establish-
14 ment (including cessation of business activities),
15 notifies the Administrator of the change.

16 (3) PROCEDURE.—Upon receipt of a completed
17 registration described in paragraph (1), the Admin-
18 istrator shall notify the registrant of the receipt of
19 the registration, designate each establishment as a
20 category 1, 2, 3, 4, or 5 food establishment, and as-
21 sign a registration number to each food establish-
22 ment and foreign food establishment.

23 (4) LIST.—The Administrator shall compile and
24 maintain an up-to-date list of food establishments
25 and foreign food establishments that are registered

1 under this section. The Administrator may establish
2 regulations by which such list may be shared with
3 other governmental authorities.

4 (5) DISCLOSURE EXEMPTION.—The disclosure
5 requirements under section 552 of title 5, United
6 States Code, shall not apply to—

7 (A) the list compiled under paragraph (4);

8 and

9 (B) information derived from the list under
10 paragraph (4), to the extent that it discloses
11 the identity or location of a specific registered
12 person.

13 (6) SUSPENSION OF REGISTRATION.—

14 (A) IN GENERAL.—The Administrator may
15 suspend the registration of a food establishment
16 or foreign food establishment, including the fa-
17 cility of an importer, for violation of a food
18 safety law.

19 (B) NOTICE AND OPPORTUNITY FOR
20 HEARING.—The Administrator shall provide no-
21 tice to a registrant immediately upon the sus-
22 pension of the registration of the facility and
23 provide registrant with an opportunity for a
24 hearing within 3 days of the suspension.

1 (7) REINSTATEMENT.—A registration that is
2 suspended under this section may be reinstated pur-
3 suant to criteria published in the Federal Register
4 by the Administrator.

5 **SEC. 203. PREVENTATIVE PROCESS CONTROLS TO REDUCE**
6 **ADULTERATION OF FOOD.**

7 (a) IN GENERAL.—The Administrator shall, upon the
8 basis of best available public health, scientific, and techno-
9 logical data, promulgate regulations to ensure that food
10 establishments carry out their responsibilities to—

11 (1) process food in a sanitary manner so that
12 it is free of dirt and filth;

13 (2) limit the presence of potentially harmful
14 contaminants in food;

15 (3) implement appropriate measures of prevent-
16 ative process control to minimize and reduce the
17 presence and growth of contaminants in food and
18 meet the performance standards established under
19 section 204;

20 (4) process all fully processed or ready-to-eat
21 food in a sanitary manner, using reasonably avail-
22 able techniques and technologies to eliminate any po-
23 tentially harmful contaminants; and

24 (5) label food intended for final processing out-
25 side commercial food establishments with instruc-

1 tions for handling and preparation for consumption
2 that will destroy contaminants.

3 (b) REGULATIONS.—Not later than 1 year after the
4 effective date of this Act, the Administrator shall promul-
5 gate regulations that—

6 (1) require all food establishments to adopt pre-
7 ventative process controls that are—

8 (A) adequate to protect the public health;

9 (B) meet relevant regulatory and food
10 safety standards; and

11 (C) limit the presence and growth of con-
12 taminants in food prepared in a food establish-
13 ment;

14 (2) set standards for sanitation;

15 (3) meet any performance standards for con-
16 taminants established under section 204;

17 (4) require recordkeeping to monitor compli-
18 ance;

19 (5) require sampling and testing at a frequency
20 and in a manner sufficient to ensure that process
21 controls are effective on an ongoing basis and that
22 regulatory standards are being met; and

23 (6) provide for agency access to records kept by
24 food establishments and submission of copies of the

1 records to the Administrator, as the Administrator
2 determines appropriate.

3 (c) PROCESSING CONTROLS.—The Administrator
4 may require any person with responsibility for or control
5 over food or food ingredients to adopt process controls,
6 if the process controls are needed to ensure the protection
7 of the public health.

8 **SEC. 204. PERFORMANCE STANDARDS FOR CONTAMINANTS**
9 **IN FOOD.**

10 (a) IN GENERAL.—To protect the public health, the
11 Administrator shall establish by regulation and enforce
12 performance standards that define, with respect to specific
13 food-borne contaminants and foods, the level of food safety
14 performance that a person responsible for producing, proc-
15 essing, or selling food shall meet.

16 (b) IDENTIFICATION OF CONTAMINANTS; PERFORM-
17 ANCE STANDARDS.—

18 (1) IN GENERAL.—Not later than 6 months
19 after the date of enactment of this Act, the Adminis-
20 trator shall identify the food-borne contaminants
21 and food that contribute significantly to the risk of
22 food-borne illness.

23 (2) PERFORMANCE STANDARDS.—As soon as
24 practicable after the identification of the contami-
25 nants under paragraph (1), the Administrator shall

1 establish appropriate performance standards to pro-
 2 tect against all food-borne contaminants.

3 (3) SIGNIFICANT CONTAMINANTS.—The Admin-
 4 istrator shall establish performance standards for
 5 the 5 contaminants that contribute to the greatest
 6 number of illnesses or deaths associated with raw
 7 meat, poultry, and seafood not later than 3 years
 8 after the date of enactment of this Act. The Admin-
 9 istrator shall revise such standards not less often
 10 than every 3 years.

11 (c) PERFORMANCE STANDARDS.—

12 (1) IN GENERAL.—The performance standards
 13 established under this section shall include—

14 (A) health-based standards that set the
 15 level of a contaminant that can safely and law-
 16 fully be present in food;

17 (B) zero tolerances, including zero toler-
 18 ances for fecal matter, in addition to any zero-
 19 tolerance standards in effect on the day before
 20 the date of enactment of this Act, when nec-
 21 essary to protect against significant adverse
 22 health outcomes;

23 (C) process standards, such as log reduc-
 24 tion criteria for cooked products, when suffi-
 25 cient to ensure the safety of processed food; and

1 (D) in the absence of data to support a
 2 performance standard described in subpara-
 3 graph (A), (B), or (C), standards that define
 4 required performance in terms of “best reason-
 5 ably achievable performance”, using best avail-
 6 able technologies, interventions, and practices.

7 (2) BEST REASONABLY ACHIEVABLE PERFORM-
 8 ANCE STANDARDS.—In developing best reasonably
 9 achievable performance standards, the Administrator
 10 shall collect, or contract for the collection of, data on
 11 current best practices and food safety outcomes re-
 12 lated to the contaminants and foods in question, as
 13 the Administrator determines necessary.

14 (3) REVOCATION BY ADMINISTRATOR.—All per-
 15 formance standards, tolerances, action levels, or
 16 other similar standards in effect on the date of en-
 17 actment of this Act shall remain in effect until re-
 18 vised or revoked by the Administrator.

19 (d) ENFORCEMENT.—

20 (1) IN GENERAL.—Not later than 1 year after
 21 the promulgation of a performance standard under
 22 this section, the Administrator shall implement a
 23 statistically significant sampling program to deter-
 24 mine whether food establishments are complying
 25 with the performance standards promulgated under

1 this section. The program established under this
 2 paragraph shall be at least as stringent as the Haz-
 3 ard Analysis and Critical Control Point System re-
 4 quirements established under part 417 of title 9,
 5 Code of Federal Regulations (or successor regula-
 6 tion).

7 (2) INSPECTIONS.—If the Administrator deter-
 8 mines that a food establishment fails to meet a
 9 standard promulgated under this section, and such
 10 establishment fails to take appropriate corrective ac-
 11 tion as determined by the Administrator, the Admin-
 12 istrator shall, as appropriate—

13 (A) detain, seize, or condemn food from
 14 the food establishment under section 402;

15 (B) order a recall of food from the food es-
 16 tablishment under section 403;

17 (C) increase the inspection frequency for
 18 the food establishment;

19 (D) withdraw the mark of inspection from
 20 the food establishment, if in use; or

21 (E) take other appropriate enforcement ac-
 22 tion concerning the food establishment, includ-
 23 ing withdrawal of registration.

24 (e) NEWLY IDENTIFIED CONTAMINANTS.—Notwith-
 25 standing any other provision of this section, the Adminis-

1 trator shall promulgate interim performance standards for
2 newly identified contaminants as necessary to protect the
3 public health.

4 **SEC. 205. INSPECTIONS OF FOOD ESTABLISHMENTS.**

5 (a) IN GENERAL.—The Administrator shall establish
6 an inspection program, which shall include sampling and
7 testing of food and food establishments, to determine if
8 each food establishment—

9 (1) is operating in a sanitary manner;

10 (2) has continuous systems, interventions, and
11 processes in place to minimize or eliminate contami-
12 nants in food;

13 (3) is in compliance with applicable perform-
14 ance standards established under section 203, and
15 other regulatory requirements;

16 (4) is processing food that is safe and not adul-
17 terated or misbranded;

18 (5) maintains records of process control plans
19 under section 203, and other records related to the
20 processing, sampling, and handling of food; and

21 (6) is in compliance with the requirements of
22 the food safety law.

23 (b) ESTABLISHMENT CATEGORIES AND INSPECTION
24 FREQUENCIES.—The resource plan required under section
25 209, including the description of resources required to

1 carry out inspections of food establishments, shall be
2 based on the following categories and inspection fre-
3 quencies, subject to subsections (c), (d), and (e):

4 (1) CATEGORY 1 FOOD ESTABLISHMENTS.—A
5 category 1 food establishment shall be subject to
6 antemortem, postmortem, and continuous inspection
7 of each slaughter line during all operating hours,
8 and other inspection on a daily basis, sufficient to
9 verify that—

10 (A) diseased animals are not offered for
11 slaughter;

12 (B) the food establishment has successfully
13 identified and removed from the slaughter line
14 visibly defective or contaminated carcasses, has
15 avoided cross-contamination, and destroyed or
16 reprocessed them in a manner acceptable to the
17 Administrator; and

18 (C) that applicable performance standards
19 and other provisions of the food safety law, in-
20 cluding those intended to eliminate or reduce
21 pathogens, have been satisfied.

22 (2) CATEGORY 2 FOOD ESTABLISHMENTS.—A
23 category 2 food establishment shall be randomly in-
24 spected at least daily.

1 (3) CATEGORY 3 FOOD ESTABLISHMENTS.—A
 2 category 3 food establishment shall—

3 (A) have ongoing verification that its proc-
 4 esses are controlled; and

5 (B) be randomly inspected at least month-
 6 ly.

7 (4) CATEGORY 4 FOOD ESTABLISHMENTS.—A
 8 category 4 food establishment shall be randomly in-
 9 spected at least quarterly.

10 (5) CATEGORY 5 FOOD ESTABLISHMENTS.—A
 11 category 5 food establishment shall be randomly in-
 12 spected at least annually.

13 (c) ESTABLISHMENT OF INSPECTION PROCE-
 14 DURES.—The Administrator shall establish procedures
 15 under which inspectors or safety officers shall take ran-
 16 dom samples, photographs, and copies of records in food
 17 establishments.

18 (d) ALTERNATIVE INSPECTION FREQUENCIES.—
 19 With respect to a category 2, 3, 4, or 5 food establishment,
 20 the Administrator may establish alternative increasing or
 21 decreasing inspection frequencies for subcategories of food
 22 establishments or individual establishments, to foster risk-
 23 based allocation of resources, subject to the following cri-
 24 teria and procedures:

1 (1) Subcategories of food establishments and
2 their alternative inspection frequencies shall be de-
3 fined by regulation, subject to paragraphs (2) and
4 (3).

5 (2) Regulations of alternative inspection fre-
6 quencies for subcategories of food establishments
7 under paragraph (1) and for a specific food estab-
8 lishment under paragraph (4) shall provide that—

9 (A) category 2 food establishments shall be
10 inspected at least monthly; and

11 (B) category 3, 4, and 5 food establish-
12 ments shall be inspected at least annually.

13 (3) In defining subcategories of food establish-
14 ments and their alternative inspection frequencies
15 under paragraphs (1) and (2), the Administrator
16 shall consider—

17 (A) the nature of the food products being
18 processed, stored, or transported;

19 (B) the manner in which food products are
20 processed, stored, or transported;

21 (C) the inherent likelihood that the prod-
22 ucts will contribute to the risk of food-borne ill-
23 ness;

24 (D) the best available evidence concerning
25 reported illnesses associated with the foods pro-

1 duced in the proposed subcategory of establish-
2 ments; and

3 (E) the overall record of compliance with
4 the food safety law among establishments in the
5 proposed subcategory, including compliance
6 with applicable performance standards and the
7 frequency of recalls.

8 (4) The Administrator may adopt alternative
9 inspection frequencies for increased or decreased in-
10 spection for a specific establishment, subject to
11 paragraphs (2) and (5) and shall periodically publish
12 a list of establishments subject to alternative inspec-
13 tions.

14 (5) In adopting alternative inspection fre-
15 quencies for a specific establishment, the Adminis-
16 trator shall consider—

17 (A) the criteria in paragraph (3);

18 (B) whether products from the specific es-
19 tablishment have been associated with a case or
20 an outbreak of food-borne illness; and

21 (C) the record of the establishment of com-
22 pliance with the food safety law, including com-
23 pliance with applicable performance standards
24 and the frequency of recalls.

1 (6) Before establishing decreased alternative in-
2 spection frequencies for subcategories of establish-
3 ments or individual establishments, the Adminis-
4 trator shall—

5 (A) determine, based on the best available
6 evidence, that the alternative uses of the re-
7 sources required to carry out the inspection ac-
8 tivity would make a greater contribution to pro-
9 tecting the public health and reducing the risk
10 of food-borne illness than the use of resources
11 described in subsection (b);

12 (B) describe the alternative uses of re-
13 sources in general terms when issuing the regu-
14 lation or order that establishes the alternative
15 inspection frequency;

16 (C) consider the supporting evidence that
17 an individual food establishment shall submit
18 related to whether an alternative inspection fre-
19 quency should be established for such establish-
20 ment by the Administrator; and

21 (D) include a description of the alternative
22 uses in the annual resource plan required in
23 section 209.

1 (e) INSPECTION TRANSITION.—The Administrator
2 shall manage the transition to the inspection system de-
3 scribed in this Act as follows:

4 (1) In the case of a category 1 or 2 food estab-
5 lishment, the Administrator shall continue to imple-
6 ment the applicable inspection mandates of the Fed-
7 eral Meat Inspection Act (21 U.S.C. 601 et seq.),
8 the Poultry Products Inspection Act (21 U.S.C. 451
9 et seq.), and the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 301 et seq.) until—

11 (A) regulations required to implement this
12 section have been promulgated;

13 (B) the performance standards required by
14 section 204(c) have been promulgated and im-
15 plemented for 1 year; and

16 (C) the establishment has achieved compli-
17 ance with the other applicable provisions of the
18 food safety law.

19 (2) In the case of a category 1 or 2 food estab-
20 lishment that, within 2 years after the promulgation
21 of the performance standards required by section
22 204(c), has not achieved compliance with the food
23 safety law, the Administrator shall—

24 (A) issue an order prohibiting the estab-
25 lishment from operating pending a demonstra-

tion by the establishment that sufficient changes in facilities, procedures, personnel, or other aspects of the process control system have been made such that the Administrator determines that compliance with the food safety law is achieved; and

(B) following the demonstration required in subparagraph (A), issue an order authorizing the food establishment to operate subject, at a minimum, to—

(i) the inspection requirement applicable to the establishment under subsection (b) (1) or (2); and

(ii) such other inspection or compliance measures determined by the Administrator necessary to assure compliance with the applicable food safety law.

(3) In the case of a category 3 food establishment, the Administrator shall continue to implement the applicable inspection mandates of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) until—

1 (A) the regulations required to implement
2 this section have been promulgated;

3 (B) the first resource plan under section
4 209 has been submitted; and

5 (C) for individual establishments, compli-
6 ance with the food safety law has been dem-
7 onstrated.

8 (4) In the case of a category 3 food establish-
9 ment that, within 1 year after the promulgation of
10 the regulations required to implement this section,
11 have not demonstrated compliance with the food
12 safety law, the Administrator shall—

13 (A) issue an order prohibiting the estab-
14 lishment from operating, pending a demonstra-
15 tion by the establishment that sufficient
16 changes in facilities, procedures, personnel, or
17 other aspects of the process control system have
18 been made such that the Administrator deter-
19 mines that compliance with the food safety law
20 is achieved; and

21 (B) following the demonstration required
22 in subparagraph (A), issue an order authorizing
23 the establishment to operate subject, at a min-
24 imum, to—

1 (i) the inspection requirement applica-
 2 ble to the establishment under subsection
 3 (b)(3); and

4 (ii) such other inspection or compli-
 5 ance measures determined by the Adminis-
 6 trator necessary to assure compliance with
 7 the food safety law.

8 (5) In the case of a category 4 or 5 food estab-
 9 lishment, the inspection requirements of this Act
 10 shall be implemented as soon as possible after—

11 (A) the promulgation of the regulations re-
 12 quired to implement this section;

13 (B) the publication of the first resource
 14 plan under section 209; and

15 (C) the commencement of the first fiscal
 16 year in which the Administration is operating
 17 with budgetary resources that Congress has ap-
 18 propriated following consideration of the re-
 19 source plan under section 209.

20 (f) OFFICIAL MARK.—

21 (1) IN GENERAL.—

22 (A) ESTABLISHMENT.—Before the comple-
 23 tion of the transition process under paragraphs
 24 (1) through (3) of subsection (e), the Adminis-
 25 trator shall by regulation establish an official

1 mark that shall be affixed to a food product
 2 produced in a category 1, 2, or 3 establishment,
 3 subject to subparagraph (B).

4 (B) PREREQUISITE.—The official mark re-
 5 quired under subparagraph (A) shall be affixed
 6 to a food product by the Administrator if the
 7 establishment has been inspected by the Admin-
 8 istrator in accordance with the inspection fre-
 9 quencies under this section and the establish-
 10 ment is in compliance with the food safety law.

11 (C) REMOVAL OF OFFICIAL MARK.—The
 12 Administrator shall promulgate regulations that
 13 provide for the removal of the official mark
 14 under this subsection if the Administrator
 15 makes a finding that the establishment is not in
 16 compliance with the food safety law.

17 (2) CATEGORY 1, 2, OR 3 FOOD ESTABLISH-
 18 MENTS.—In the case of products produced in a cat-
 19 egory 1, 2, or 3 food establishment—

20 (A) products subject to Federal Meat In-
 21 spection Act (21 U.S.C. 601 et seq.), the Poul-
 22 try Products Inspection Act (21 U.S.C. 451 et
 23 seq.), the Egg Products Inspection Act (21
 24 U.S.C. 1031 et seq.), and the Federal Food,
 25 Drug, and Cosmetic Act (21 U.S.C. 301 et

1 seq.) as of the date of enactment of this Act
 2 shall remain subject to the requirement under
 3 those Acts that they bear the mark of inspec-
 4 tion pending completion of the transition proc-
 5 ess under paragraphs (1) through (3) of sub-
 6 section (e);

7 (B) the Administrator shall publicly certify
 8 on a monthly basis that the inspection fre-
 9 quencies required under this Act have been
 10 achieved; and

11 (C) a product from an establishment that
 12 has not been inspected in accordance with the
 13 required frequencies under this section shall not
 14 bear the official mark and shall not be shipped
 15 in interstate commerce.

16 (3) CATEGORY 4 AND 5 FOOD ESTABLISH-
 17 MENTS.—In the case of a product produced in a cat-
 18 egory 4 or 5 food establishment the Administrator
 19 shall provide by regulation for the voluntary use of
 20 the official mark established under paragraph (1),
 21 subject to—

22 (A) such minimum inspection frequencies
 23 as determined appropriate by the Adminis-
 24 trator;

1 (B) compliance with applicable perform-
2 ance standards and other provisions of the food
3 safety law; and

4 (C) such other requirements the Adminis-
5 trator considers appropriate.

6 (g) IMPLEMENTATION.—Not later than 1 year after
7 the effective date of this Act, the Administrator shall issue
8 regulations to implement subsections (b) through (e).

9 (h) MAINTENANCE AND INSPECTION OF RECORDS.—

10 (1) IN GENERAL.—

11 (A) RECORDS.—A food establishment
12 shall—

13 (i) maintain such records as the Ad-
14 ministrator shall require by regulation, in-
15 cluding all records relating to the proc-
16 essing, distributing, receipt, or importation
17 of any food; and

18 (ii) permit the Administrator, in addi-
19 tion to any authority of the food safety
20 agencies in effect on the day before the
21 date of enactment of this Act, upon pres-
22 entation of appropriate credentials and at
23 reasonable times and in a reasonable man-
24 ner, to have access to and copy all records
25 maintained by or on behalf of such food es-

1 tablishment representative in any format
2 (including paper or electronic) and at any
3 location, that are necessary to assist the
4 Administrator—

5 (I) to determine whether the food
6 is contaminated or not in compliance
7 with the food safety law; or

8 (II) to track the food in com-
9 merce.

10 (B) REQUIRED DISCLOSURE.—A food es-
11 tablishment shall have an affirmative obligation
12 to disclose to the Administrator the results of
13 testing or sampling of food, equipment, or ma-
14 terial in contact with food, that is positive for
15 any contaminant.

16 (2) MAINTENANCE OF RECORDS.—The records
17 in paragraph (1) shall be maintained for a reason-
18 able period of time, as determined by the Adminis-
19 trator.

20 (3) REQUIREMENTS.—The records in para-
21 graph (1) shall include records describing—

22 (A) the origin, receipt, delivery, sale, move-
23 ment, holding, and disposition of food or ingre-
24 dients;

1 (B) the identity and quantity of ingredi-
2 ents used in the food;

3 (C) the processing of the food;

4 (D) the results of laboratory, sanitation, or
5 other tests performed on the food or in the food
6 establishment;

7 (E) consumer complaints concerning the
8 food or packaging of the food;

9 (F) the production codes, open date codes,
10 and locations of food production; and

11 (G) other matters reasonably related to
12 whether food is unsafe, is adulterated or mis-
13 branded, or otherwise fails to meet the require-
14 ments of this Act.

15 (i) PROTECTION OF SENSITIVE INFORMATION.—

16 (1) IN GENERAL.—The Administrator shall de-
17 velop and maintain procedures to prevent the unau-
18 thorized disclosure of any trade secret or confiden-
19 tial information obtained by the Administrator.

20 (2) LIMITATION.—The requirement under this
21 subsection does not—

22 (A) limit the authority of the Adminis-
23 trator to inspect or copy records or to require
24 the establishment or maintenance of records
25 under this Act;

1 (B) have any legal effect on section 1905
2 of title 18, United States Code;

3 (C) extend to any food recipe, financial
4 data, pricing data, personnel data, or sales data
5 (other than shipment dates relating to sales);

6 (D) limit the public disclosure of distribu-
7 tion records or other records related to food
8 subject to a voluntary or mandatory recall
9 under section 403; or

10 (E) limit the authority of the Adminis-
11 trator to promulgate regulations to permit the
12 sharing of data with other governmental au-
13 thorities.

14 (j) BRIBERY OF OR GIFTS TO INSPECTOR OR OTHER
15 OFFICERS AND ACCEPTANCE OF GIFTS.—Section 22 of
16 the Federal Meat Inspection Act (21 U.S.C. 622) shall
17 apply under this Act.

18 **SEC. 206. FOOD PRODUCTION FACILITIES.**

19 In carrying out the duties of the Administrator and
20 the purposes of this Act, the Administrator shall have the
21 authority, with respect to food production facilities, to—

22 (1) visit and inspect food production facilities in
23 the United States and in foreign countries to inves-
24 tigate bioterrorism threats and for other critical food
25 safety purposes;

1 (2) review food safety records as required to be
2 kept by the Administrator to carry out traceback
3 and for other critical food safety purposes;

4 (3) set good practice standards to protect the
5 public and animal health and promote food safety;

6 (4) conduct monitoring and surveillance of ani-
7 mals, plants, products, or the environment, as ap-
8 propriate; and

9 (5) collect and maintain information relevant to
10 public health and farm practices.

11 **SEC. 207. FEDERAL AND STATE COOPERATION.**

12 (a) IN GENERAL.—The Administrator shall work
13 with the States to carry out activities and programs that
14 create a national food safety program so that Federal and
15 State programs function in a coordinated and cost-effec-
16 tive manner.

17 (b) STATE ACTION.—The Administrator shall work
18 with States to—

19 (1) continue, strengthen, or establish State food
20 safety programs, especially with respect to the regu-
21 lation of retail commercial food establishments,
22 transportation, harvesting, and fresh markets;

23 (2) continue, strengthen, or establish inspection
24 programs and requirements to ensure that food
25 under the jurisdiction of the State is safe; and

1 (3) support recall authorities at the State and
2 local levels.

3 (c) ASSISTANCE.—To assist in planning, developing,
4 and implementing a food safety program, the Adminis-
5 trator may provide and continue to a State—

6 (1) advisory assistance;

7 (2) technical and laboratory assistance and
8 training (including necessary materials and equip-
9 ment); and

10 (3) financial, in kind, and other aid.

11 (d) SERVICE AGREEMENTS.—

12 (1) IN GENERAL.—The Administrator may,
13 under agreements entered into with Federal, State,
14 or local agencies, use on a reimbursable basis or oth-
15 erwise, the personnel and services of those agencies
16 in carrying out this Act.

17 (2) TRAINING.—Agreements with a State under
18 this subsection may provide for training of State em-
19 ployees.

20 (3) MAINTENANCE OF AGREEMENTS.—The Ad-
21 ministrator shall maintain any agreement that is in
22 effect on the day before the date of enactment of
23 this Act until the Administrator evaluates such
24 agreement and determines whether to maintain or
25 substitute such agreement.

1 (e) AUDITS.—

2 (1) IN GENERAL.—The Administrator shall an-
 3 nually conduct a comprehensive review of each State
 4 program that provides services to the Administrator
 5 in carrying out the responsibilities under this Act,
 6 including mandated inspections under section 205.

7 (2) REQUIREMENTS.—The review shall—

8 (A) include a determination of the effec-
 9 tiveness of the State program; and

10 (B) identify any changes necessary to en-
 11 sure enforcement of Federal requirements
 12 under this Act.

13 (f) NO FEDERAL PREEMPTION.—Nothing in this Act
 14 shall be construed to preempt the enforcement of State
 15 food safety laws and standards that are at least as strin-
 16 gent as those under this Act.

17 **SEC. 208. IMPORTS.**

18 (a) IN GENERAL.—Not later than 2 years after the
 19 effective date of this Act, the Administrator shall establish
 20 a system under which a foreign government or foreign
 21 food establishment seeking to import food to the United
 22 States shall submit a request for certification to the Ad-
 23 ministrator.

24 (b) CERTIFICATION STANDARD.—A foreign govern-
 25 ment or foreign food establishment requesting a certifi-

1 cation to import food to the United States shall dem-
 2 onstrate, in a manner determined appropriate by the Ad-
 3 ministrator, that food produced under the supervision of
 4 a foreign government or by the foreign food establishment
 5 has met standards for food safety, inspection, labeling,
 6 and consumer protection that are at least equivalent to
 7 standards applicable to food produced in the United
 8 States.

9 (c) CERTIFICATION APPROVAL.—

10 (1) REQUEST BY FOREIGN GOVERNMENT.—

11 Prior to granting the certification request of a for-
 12 eign government, the Administrator shall review,
 13 audit, and certify the food safety program of a re-
 14 questing foreign government (including all statutes,
 15 regulations, and inspection authority) as at least
 16 equivalent to the food safety program in the United
 17 States, as demonstrated by the foreign government.

18 (2) REQUEST BY FOREIGN FOOD ESTABLISH-

19 MENT.—Prior to granting the certification request of
 20 a foreign food establishment, the Administrator shall
 21 certify, based on an onsite inspection, the food safe-
 22 ty programs and procedures of a requesting foreign
 23 firm as at least equivalent to the food safety pro-
 24 grams and procedures of the United States.

1 (d) LIMITATION.—A foreign government or foreign
2 firm approved by the Administrator to import food to the
3 United States under this section shall be certified to ex-
4 port only the approved food products to the United States
5 for a period not to exceed 5 years.

6 (e) WITHDRAWAL OF CERTIFICATION.—The Admin-
7 istrator may withdraw certification of any food from a for-
8 eign government or foreign firm—

9 (1) if such food is linked to an outbreak of
10 human illness;

11 (2) following an investigation by the Adminis-
12 trator that finds that the foreign government pro-
13 grams and procedures or foreign food establishment
14 is no longer equivalent to the food safety programs
15 and procedures in the United States; or

16 (3) following a refusal to allow United States
17 officials to conduct such audits and investigations as
18 may be necessary to fulfill the requirements under
19 this section.

20 (f) RENEWAL OF CERTIFICATION.—The Adminis-
21 trator shall audit foreign governments and foreign food
22 establishments at least every 5 years to ensure the contin-
23 ued compliance with the standards set forth in this sec-
24 tion.

1 (g) REQUIRED ROUTINE INSPECTION.—The Admin-
2 istrator shall routinely inspect food and food animals (via
3 a physical examination) before it enters the United States
4 to ensure that it is—

5 (1) safe;

6 (2) labeled as required for food produced in the
7 United States; and

8 (3) otherwise meets requirements under the
9 food safety law.

10 (h) ENFORCEMENT.—The Administrator is author-
11 ized to—

12 (1) deny importation of food from any foreign
13 government that does not permit United States offi-
14 cials to enter the foreign country to conduct such
15 audits and inspections as may be necessary to fulfill
16 the requirements under this section;

17 (2) deny importation of food from any foreign
18 government or foreign firm that does not consent to
19 an investigation by the Administration when food
20 from that foreign country or foreign firm is linked
21 to a food-borne illness outbreak or is otherwise
22 found to be adulterated or mislabeled; and

23 (3) promulgate rules and regulations to carry
24 out the purposes of this section, including setting

1 terms and conditions for the destruction of products
2 that fail to meet the standards of this Act.

3 (i) DETENTION AND SEIZURE.—Any food imported
4 for consumption in the United States may be detained,
5 seized, or condemned pursuant to section 402.

6 **SEC. 209. RESOURCE PLAN.**

7 (a) IN GENERAL.—The Administrator shall prepare
8 and update annually a resource plan describing the re-
9 sources required, in the best professional judgment of the
10 Administrator, to develop and fully implement the national
11 food safety program established under this Act.

12 (b) CONTENTS OF PLAN.—The resource plan shall—

13 (1) describe quantitatively the personnel, finan-
14 cial, and other resources required to carry out the
15 inspection of food establishments under section 205
16 and other requirements of the national food safety
17 program;

18 (2) allocate inspection resources in a manner
19 reflecting the distribution of risk and opportunities
20 to reduce risk across the food supply to the extent
21 feasible based on the best available information, and
22 subject to section 205; and

23 (3) describe the personnel, facilities, equipment,
24 and other resources needed to carry out inspection
25 and other oversight activities, at a total resource

1 level equal to at least 50 percent of the resources re-
2 quired to carry out inspections in food establish-
3 ments under section 205—

4 (A) in foreign establishments;

5 (B) at the point of importation; and

6 (C) at the point of production on farms,
7 ranches, and feedlots.

8 (c) GRANTS.—The resource plan shall include rec-
9 ommendations for funding to provide grants to States and
10 local governments to carry out food safety activities in re-
11 tail and food service facilities and the required inspections
12 in food establishments.

13 (d) SUBMISSION OF PLAN.—The Administrator shall
14 submit annually to the Committee on Appropriations of
15 the Senate, the Committee on Appropriations of the House
16 of Representatives, and other relevant committees of Con-
17 gress, the resource plan required under this section.

18 **SEC. 210. TRACEBACK.**

19 (a) IN GENERAL.—The Administrator, in order to
20 protect the public health, shall establish requirements for
21 a national system for tracing food and food producing ani-
22 mals from point of origin to retail sale, subject to sub-
23 section (b).

24 (b) APPLICABILITY.—Traceability requirements
25 shall—

1 (1) be established in accordance with regula-
 2 tions and guidelines issued by the Administrator;
 3 and

4 (2) apply to food production facilities and food
 5 establishments.

6 (c) RELATIONSHIP TO COUNTRY OF ORIGIN LABEL-
 7 ING.—Nothing contained in this section prevents or inter-
 8 feres with implementation of the country of origin labeling
 9 requirements of subtitle D of the Agricultural Marketing
 10 Act of 1946 (7 U.S.C. 1638 et seq.).

11 **TITLE III—RESEARCH AND** 12 **EDUCATION**

13 **SEC. 301. PUBLIC HEALTH ASSESSMENT SYSTEM.**

14 (a) IN GENERAL.—The Administrator, acting in co-
 15 ordination with the Director of the Centers for Disease
 16 Control and Prevention and with the Research Education
 17 and Economics mission area of the Department of Agri-
 18 culture, shall—

19 (1) have access to the applicable data systems
 20 of the Centers for Disease Control and Prevention
 21 and to the databases made available by a State;

22 (2) maintain an active surveillance system of
 23 food, food products, and epidemiological evidence
 24 submitted by States to the Centers for Disease Con-

1 trol and Prevention based on a representative pro-
 2 portion of the population of the United States;

3 (3) assess the frequency and sources of human
 4 illness in the United States associated with the con-
 5 sumption of food;

6 (4) maintain a state-of-the-art DNA matching
 7 system and epidemiological system dedicated to food-
 8 borne illness identification, outbreaks, and contain-
 9 ment; and

10 (5) have access to the surveillance data created
 11 via monitoring and statistical studies conducted as
 12 part of its own inspection.

13 (b) PUBLIC HEALTH SAMPLING.—

14 (1) IN GENERAL.—Not later than 1 year after
 15 the effective date of this Act, the Administrator shall
 16 establish guidelines for a sampling system under
 17 which the Administrator shall take and analyze sam-
 18 ples of food—

19 (A) to assist the Administrator in carrying
 20 out this Act; and

21 (B) to assess the nature, frequency of oc-
 22 currence, and quantities of contaminants in
 23 food.

24 (2) REQUIREMENTS.—The sampling system de-
 25 scribed in paragraph (1) shall provide—

1 (A) statistically valid monitoring, including
2 market-based studies, on the nature, frequency
3 of occurrence, and quantities of contaminants
4 in food available to consumers; and

5 (B) at the request of the Administrator,
6 such other information, including analysis of
7 monitoring and verification samples, as the Ad-
8 ministrator determines may be useful in assess-
9 ing the occurrence of contaminants in food.

10 (c) ASSESSMENT OF HEALTH HAZARDS.—

11 (1) IN GENERAL.—Through the surveillance
12 system referred to in subsection (a) and the sam-
13 pling system described in subsection (b), the Admin-
14 istrator shall—

15 (A) rank food categories based on the haz-
16 ard to human health presented by the food cat-
17 egory;

18 (B) identify appropriate industry and regu-
19 latory approaches to minimize hazards in the
20 food supply; and

21 (C) assess the public health environment
22 for emerging diseases, including zoonosis, for
23 their risk of appearance in the United States
24 food supply.

1 (2) COMPONENTS OF ANALYSIS.—The analysis
2 under subsection (b)(1) may include—

3 (A) a comparison of the safety of commer-
4 cial processing with the health hazards associ-
5 ated with food that is harvested for recreational
6 or subsistence purposes and prepared non-
7 commercially;

8 (B) a comparison of the safety of food that
9 is domestically processed with the health haz-
10 ards associated with food that is processed out-
11 side the United States;

12 (C) a description of contamination origi-
13 nating from handling practices that occur prior
14 to or after the sale of food to consumers; and

15 (D) use of comparative risk assessments.

16 **SEC. 302. PUBLIC EDUCATION AND ADVISORY SYSTEM.**

17 (a) PUBLIC EDUCATION.—

18 (1) IN GENERAL.—The Administrator, in co-
19 operation with private and public organizations, in-
20 cluding the cooperative extension services and build-
21 ing on the efforts of appropriate State and local en-
22 tities, shall establish a national public education pro-
23 gram on food safety.

24 (2) REQUIREMENTS.—The program shall pro-
25 vide—

1 (A) information to the public regarding
2 Federal standards and best practices and pro-
3 motion of public awareness, understanding, and
4 acceptance of those standards and practices;

5 (B) information for health professionals—

6 (i) to improve diagnosis and treatment
7 of food-related illness; and

8 (ii) to advise individuals at special
9 risk for food-related illnesses; and

10 (C) such other information or advice to
11 consumers and other persons as the Adminis-
12 trator determines will promote the purposes of
13 this Act.

14 (b) HEALTH ADVISORIES.—The Administrator, in
15 consultation with other Federal departments and agencies
16 as the Administrator determines necessary, shall work
17 with the States and other appropriate entities—

18 (1) to develop and distribute regional and na-
19 tional advisories concerning food safety;

20 (2) to develop standardized formats for written
21 and broadcast advisories;

22 (3) to incorporate State and local advisories
23 into the national public education program estab-
24 lished under subsection (a); and

1 (4) to present prompt, specific information re-
2 garding foods found to pose a threat to the public
3 health.

4 **SEC. 303. RESEARCH.**

5 (a) IN GENERAL.—The Administrator shall conduct
6 research to carry out this Act, including studies to—

7 (1) improve sanitation and food safety practices
8 in the processing of food;

9 (2) develop improved techniques to monitor and
10 inspect food;

11 (3) develop efficient, rapid, and sensitive meth-
12 ods to detect contaminants in food;

13 (4) determine the sources of contamination of
14 contaminated food;

15 (5) develop food consumption data;

16 (6) identify ways that animal production tech-
17 niques could improve the safety of the food supply;

18 (7) draw upon research and educational pro-
19 grams that exist at the State and local level;

20 (8) utilize the DNA matching system and other
21 processes to identify and control pathogens;

22 (9) address common and emerging zoonotic dis-
23 eases;

1 (10) develop methods to reduce or destroy
2 harmful pathogens before, during, and after proc-
3 essing;

4 (11) analyze the incidence of antibiotic
5 resistance as it pertains to the food supply and de-
6 velop new methods to reduce the transfer of anti-
7 biotic resistance to humans; and

8 (12) conduct other research that supports the
9 purposes of this Act.

10 (b) CONTRACT AUTHORITY.—The Administrator may
11 enter into contracts and agreements with any State, uni-
12 versity, Federal Government agency, or person to carry
13 out this section.

14 **TITLE IV—ENFORCEMENT**

15 **SEC. 401. PROHIBITED ACTS.**

16 It is prohibited—

17 (1) to manufacture, introduce, deliver for intro-
18 duction, or receive into interstate commerce any food
19 that is adulterated, misbranded, or otherwise unsafe;

20 (2) to adulterate or misbrand any food in inter-
21 state commerce;

22 (3) for a food establishment or foreign food es-
23 tablishment to fail to register under section 202, or
24 to operate without a valid registration;

1 (4) to refuse to permit access to a food estab-
2 lishment for the inspection and copying of a record
3 as required under section 205(h);

4 (5) to fail to establish or maintain any record
5 or to make any report as required under section
6 205(h);

7 (6) to refuse to permit entry to or inspection of
8 a food establishment as required under section 205;

9 (7) to fail to provide to the Administrator the
10 results of a testing or sampling of a food, equip-
11 ment, or material in contact with contaminated food
12 under section 205(i);

13 (8) to fail to comply with a provision, regula-
14 tion, or order of the Administrator under section
15 202, 203, 204, or 208;

16 (9) to slaughter an animal that is capable for
17 use in whole or in part as human food at a food es-
18 tablishment processing any such food for commerce,
19 except in compliance with the food safety law;

20 (10) to transfer food in violation of an adminis-
21 trative detention order under section 402 or to re-
22 move or alter a required mark or label identifying
23 the food as detained;

24 (11) to fail to comply with a recall or other
25 order under section 403; or

1 (12) to otherwise violate the food safety law.

2 **SEC. 402. FOOD DETENTION, SEIZURE, AND CONDEMNATION.**
3

4 (a) ADMINISTRATIVE DETENTION OF FOOD.—

5 (1) EXPANDED AUTHORITY.—The Adminis-
6 trator shall have authority under section 304 of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 334) to administratively detain and seize any food
9 that the Administrator has reason to believe is un-
10 safe, is adulterated or misbranded, or otherwise fails
11 to meet the requirements of the food safety law.

12 (2) DETENTION AUTHORITY.—If, during an in-
13 spection conducted in accordance with section 205 or
14 208, an officer, employee, or agent of the Adminis-
15 tration making the inspection has reason to believe
16 that a domestic food, imported food, or food offered
17 for import is unsafe, is adulterated or misbranded,
18 or otherwise fails to meet the requirements of this
19 Act, the officer or employee may order the food de-
20 tained.

21 (3) PERIOD OF DETENTION.—

22 (A) IN GENERAL.—A food may be detained
23 for a reasonable period, not to exceed 20 days,
24 unless a longer period, not to exceed 30 days,

1 is necessary for the Administrator to institute a
2 seizure action.

3 (B) PERISHABLE FOOD.—The Adminis-
4 trator shall provide by regulation for procedures
5 to institute a seizure action on an expedited
6 basis with respect to perishable food.

7 (4) SECURITY OF DETAINED FOOD.—

8 (A) IN GENERAL.—A detention order—

9 (i) may require that the food be la-
10 beled or marked as detained; and

11 (ii) shall require that the food be re-
12 moved to a secure facility, if appropriate.

13 (B) FOOD SUBJECT TO AN ORDER.—A
14 food subject to a detention order shall not be
15 transferred by any person from the place at
16 which the food is removed, until released by the
17 Administrator or until the expiration of the de-
18 tention period applicable under the order,
19 whichever occurs first.

20 (C) DELIVERY OF FOOD.—This subsection
21 does not authorize the delivery of a food in ac-
22 cordance with execution of a bond while the ar-
23 ticle is subject to the order.

24 (b) APPEAL OF DETENTION ORDER.—

1 (1) IN GENERAL.—A person who would be enti-
 2 tled to be a claimant for a food subject to a deten-
 3 tion order if the food were seized under section 304
 4 of the Federal Food, Drug, and Cosmetic Act (21
 5 U.S.C. 334), may appeal the order to the Adminis-
 6 trator.

7 (2) ACTION BY THE ADMINISTRATOR.—Not
 8 later than 5 days after an appeal is filed under para-
 9 graph (1), the Administrator, after providing an op-
 10 portunity for an informal hearing, shall confirm,
 11 modify, or terminate the order involved.

12 (3) FINAL AGENCY ACTION.—Confirmation,
 13 modification, or termination by the Administrator
 14 under paragraph (2) shall be considered a final
 15 agency action for purposes of section 702 of title 5,
 16 United States Code.

17 (4) TERMINATION.—The order shall be consid-
 18 ered to be terminated if, after 5 days, the Adminis-
 19 trator has failed—

20 (A) to provide an opportunity for an infor-
 21 mal hearing; or

22 (B) to confirm, modify, or terminate the
 23 order.

24 (5) EFFECT OF INSTITUTING COURT ACTION.—
 25 If the Administrator initiates an action under sec-

tion 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) or section 304(a) of that Act (21 U.S.C. 334(a)), the process for the appeal of the detention order shall terminate.

(c) CONDEMNATION OF FOOD.—

(1) IN GENERAL.—After confirming a detention order, the Administrator may order the food condemned.

(2) DESTRUCTION OF FOOD.—Any food condemned shall be destroyed under the supervision of the Administrator.

(3) RELEASE OF FOOD.—If the Administrator determines that, through reprocessing, relabeling, or other action, a detained food can be brought into compliance with this Act, the food may be released following a determination by the Administrator that the relabeling or other action as specified by the Administrator has been performed.

(d) TEMPORARY HOLDS AT PORTS OF ENTRY.—

(1) IN GENERAL.—If an officer or qualified employee of the Administration has reason to believe that a food is unsafe, is adulterated or misbranded, or otherwise fails to meet the requirements of this Act, and the officer or qualified employee is unable to inspect, examine, or investigate the food when the

1 food is offered for import at a port of entry into the
2 United States, the officer or qualified employee shall
3 request the Secretary of Homeland Security to hold
4 the food at the port of entry for a reasonable period
5 of time, not to exceed 24 hours, to enable the Ad-
6 ministrator to inspect or investigate the food as ap-
7 propriate.

8 (2) REMOVAL TO SECURE FACILITY.—The Ad-
9 ministrator shall work in coordination with the Sec-
10 retary of Homeland Security to remove a food held
11 in accordance with paragraph (1) to a secure facility
12 as appropriate.

13 (3) PROHIBITION ON TRANSFER.—During the
14 period in which the food is held, the food shall not
15 be transferred by any person from the port of entry
16 into the United States, or from the secure facility to
17 which the food has been removed.

18 (4) DELIVERY IN ACCORDANCE WITH A
19 BOND.—The delivery of the food in accordance with
20 the execution of a bond while the food is held is not
21 authorized.

22 (5) PROHIBITION ON REEXPORT.—A food
23 found unfit for human or animal consumption shall
24 be prohibited from reexport without further proc-

1 essing to remove the contamination and reinspection
2 by the Administration.

3 **SEC. 403. NOTIFICATION AND RECALL.**

4 (a) NOTICE TO ADMINISTRATOR OF VIOLATION.—

5 (1) IN GENERAL.—A person that has reason to
6 believe that any food introduced into or in interstate
7 commerce, or held for sale (whether or not the first
8 sale) after shipment in interstate commerce, may be
9 in violation of the food safety law shall immediately
10 notify the Administrator of the identity and location
11 of the food.

12 (2) MANNER OF NOTIFICATION.—Notification
13 under paragraph (1) shall be made in such manner
14 and by such means as the Administrator may re-
15 quire by regulation.

16 (b) RECALL AND CONSUMER NOTIFICATION.—

17 (1) VOLUNTARY ACTIONS.—If the Adminis-
18 trator determines that food is in violation of the food
19 safety law when introduced into or while in inter-
20 state commerce or while held for sale (whether or
21 not the first sale) after shipment in interstate com-
22 merce and that there is a reasonable probability that
23 the food, if consumed, would present a threat to
24 public health, as determined by the Administrator,
25 the Administrator shall give the appropriate persons

(including the manufacturers, importers, distributors, or retailers of the food) an opportunity to—

(A) cease distribution of the food;

(B) notify all persons—

(i) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or

(ii) to which the food has been distributed, transported, or sold, to immediately cease distribution of the food;

(C) recall the food;

(D) in conjunction with the Administrator, provide notice of the finding of the Administrator—

(i) to consumers to whom the food was, or may have been, distributed; and

(ii) to State and local public health officials; or

(E) take any combination of the measures described in this paragraph, as determined by the Administrator to be appropriate in the circumstances.

(2) MANDATORY ACTIONS.—If a person referred to in paragraph (1) refuses to or does not

1 adequately carry out the actions described in that
2 paragraph within the time period and in the manner
3 prescribed by the Administrator, the Administrator
4 shall—

5 (A) have authority to control and possess
6 the food, including ordering the shipment of the
7 food from the food establishment to the Admin-
8 istrator—

9 (i) at the expense of the food estab-
10 lishment; or

11 (ii) in an emergency (as determined
12 by the Administrator), at the expense of
13 the Administration; and

14 (B) by order, require, as the Administrator
15 determines to be necessary, the person to imme-
16 diately—

17 (i) cease distribution of the food; and

18 (ii) notify all persons—

19 (I) processing, distributing, or
20 otherwise handling the food to imme-
21 diately cease such activities with re-
22 spect to the food; or

23 (II) if the food has been distrib-
24 uted, transported, or sold, to imme-
25 diately cease distribution of the food.

1 (3) NOTIFICATION TO CONSUMERS BY ADMINIS-
2 TRATOR.—The Administrator shall, as the Adminis-
3 trator determines to be necessary, provide notice of
4 the finding of the Administrator under paragraph
5 (1)—

6 (A) to consumers to whom the food was, or
7 may have been, distributed; and

8 (B) to State and local public health offi-
9 cials.

10 (4) NONDISTRIBUTION BY NOTIFIED PER-
11 SONS.—A person that processes, distributes, or oth-
12 erwise handles the food, or to which the food has
13 been distributed, transported, or sold, and that is
14 notified under paragraph (1)(B) or (2)(B) shall im-
15 mediately cease distribution of the food.

16 (5) AVAILABILITY OF RECORDS TO ADMINIS-
17 TRATOR.—Each person referred to in paragraph (1)
18 that processed, distributed, or otherwise handled
19 food shall make available to the Administrator infor-
20 mation necessary to carry out this subsection, as de-
21 termined by the Administrator, regarding—

22 (A) persons that processed, distributed, or
23 otherwise handled the food; and

1 (B) persons to which the food has been
2 transported, sold, distributed, or otherwise han-
3 dled.

4 (c) INFORMAL HEARINGS ON ORDERS.—

5 (1) IN GENERAL.—The Administrator shall pro-
6 vide any person subject to an order under subsection
7 (b) with an opportunity for an informal hearing, to
8 be held as soon as practicable but not later than 2
9 business days after the issuance of the order.

10 (2) SCOPE OF THE HEARING.—In a hearing
11 under paragraph (1), the Administrator shall con-
12 sider the actions required by the order and any rea-
13 sons why the food that is the subject of the order
14 should not be recalled.

15 (d) POST-HEARING RECALL ORDERS.—

16 (1) AMENDMENT OF ORDER.—If, after pro-
17 viding an opportunity for an informal hearing under
18 subsection (c), the Administrator determines that
19 there is a reasonable probability that the food that
20 is the subject of an order under subsection (b), if
21 consumed, would present a threat to the public
22 health, the Administrator, as the Administrator de-
23 termines to be necessary, may—

24 (A) amend the order to require recall of
25 the food or other appropriate action;

1 (B) specify a timetable in which the recall
2 shall occur;

3 (C) require periodic reports to the Admin-
4 istrator describing the progress of the recall;
5 and

6 (D) provide notice of the recall to con-
7 sumers to whom the food was, or may have
8 been, distributed.

9 (2) VACATION OF ORDERS.—If, after providing
10 an opportunity for an informal hearing under sub-
11 section (c), the Administrator determines that ade-
12 quate grounds do not exist to continue the actions
13 required by the order, the Administrator shall vacate
14 the order.

15 (e) REMEDIES NOT EXCLUSIVE.—The remedies pro-
16 vided in this section shall be in addition to, and not exclu-
17 sive of, other remedies that may be available.

18 **SEC. 404. INJUNCTION PROCEEDINGS.**

19 (a) JURISDICTION.—The district courts of the United
20 States, and the United States courts of the territories and
21 possessions of the United States, shall have jurisdiction,
22 for cause shown, to restrain a violation of section 202,
23 203, 204, 207, or 401 (or a regulation promulgated under
24 that section).

1 (b) TRIAL.—In a case in which violation of an injunc-
 2 tion or restraining order issued under this section also
 3 constitutes a violation of the food safety law, trial shall
 4 be by the court or, upon demand of the accused, by a jury.

5 **SEC. 405. CIVIL AND CRIMINAL PENALTIES.**

6 (a) CIVIL SANCTIONS.—

7 (1) CIVIL PENALTY.—

8 (A) IN GENERAL.—Any person that com-
 9 mits an act that violates the food safety law (in-
 10 cluding a regulation promulgated or order
 11 issued under a Federal food safety law) may be
 12 assessed a civil penalty by the Administrator of
 13 not more than \$10,000 for each such act.

14 (B) SEPARATE OFFENSE.—Each act de-
 15 scribed in subparagraph (A) and each day dur-
 16 ing which that act continues shall be considered
 17 a separate offense.

18 (2) OTHER REQUIREMENTS.—

19 (A) WRITTEN ORDER.—The civil penalty
 20 described in paragraph (1) shall be assessed by
 21 the Administrator by a written order, which
 22 shall specify the amount of the penalty and the
 23 basis for the penalty under subparagraph (B)
 24 considered by the Administrator.

1 (B) AMOUNT OF PENALTY.—Subject to
2 paragraph (1)(A), the amount of the civil pen-
3 alty shall be determined by the Administrator,
4 after considering—

5 (i) the gravity of the violation;

6 (ii) the degree of culpability of the
7 person;

8 (iii) the size and type of the business
9 of the person; and

10 (iv) any history of prior offenses by
11 the person under the food safety law.

12 (C) REVIEW OF ORDER.—The order may
13 be reviewed only in accordance with subsection
14 (c).

15 (b) CRIMINAL SANCTIONS.—

16 (1) IN GENERAL.—Except as provided in para-
17 graphs (2) and (3), a person that knowingly pro-
18 duces or introduces into commerce food that is un-
19 safe or otherwise adulterated or misbranded shall be
20 imprisoned for not more than 1 year or fined not
21 more than \$10,000, or both.

22 (2) SEVERE VIOLATIONS.—A person that com-
23 mits a violation described in paragraph (1) after a
24 conviction of that person under this section has be-
25 come final, or commits such a violation with the in-

1 tent to defraud or mislead, shall be imprisoned for
2 not more than 3 years or fined not more than
3 \$100,000, or both.

4 (3) EXCEPTION.—No person shall be subject to
5 the penalties of this subsection—

6 (A) for having received, proffered, or deliv-
7 ered in interstate commerce any food, if the re-
8 ceipt, proffer, or delivery was made in good
9 faith, unless that person refuses to furnish (on
10 request of an officer or employee designated by
11 the Administrator)—

12 (i) the name, address and contact in-
13 formation of the person from whom that
14 person purchased or received the food;

15 (ii) copies of all documents relating to
16 the person from whom that person pur-
17 chased or received the food; and

18 (iii) copies of all documents pertaining
19 to the delivery of the food to that person;
20 or

21 (B) if that person establishes a guaranty
22 signed by, and containing the name and address
23 of, the person from whom that person received
24 in good faith the food, stating that the food is

1 not adulterated or misbranded within the mean-
2 ing of this Act.

3 (c) JUDICIAL REVIEW.—

4 (1) IN GENERAL.—An order assessing a civil
5 penalty under subsection (a) shall be a final order
6 unless the person—

7 (A) not later than 30 days after the effec-
8 tive date of the order, files a petition for judi-
9 cial review of the order in the United States
10 court of appeals for the circuit in which that
11 person resides or has its principal place of busi-
12 ness or the United States Court of Appeals for
13 the District of Columbia; and

14 (B) simultaneously serves a copy of the pe-
15 tition by certified mail to the Administrator.

16 (2) FILING OF RECORD.—Not later than 45
17 days after the service of a copy of the petition under
18 paragraph (1)(B), the Administrator shall file in the
19 court a certified copy of the administrative record
20 upon which the order was issued.

21 (3) STANDARD OF REVIEW.—The findings of
22 the Administrator relating to the order shall be set
23 aside only if found to be unsupported by substantial
24 evidence on the record as a whole.

25 (d) COLLECTION ACTIONS FOR FAILURE TO PAY.—

1 (1) IN GENERAL.—If any person fails to pay a
 2 civil penalty assessed under subsection (a) after the
 3 order assessing the penalty has become a final order,
 4 or after the court of appeals described in subsection
 5 (b) has entered final judgment in favor of the Ad-
 6 ministrator, the Administrator shall refer the matter
 7 to the Attorney General, who shall institute in a
 8 United States district court of competent jurisdic-
 9 tion a civil action to recover the amount assessed.

10 (2) LIMITATION ON REVIEW.—In a civil action
 11 under paragraph (1), the validity and appropriate-
 12 ness of the order of the Administrator assessing the
 13 civil penalty shall not be subject to judicial review.

14 (e) PENALTIES PAID INTO ACCOUNT.—The Adminis-
 15 trator—

16 (1) shall deposit penalties collected under this
 17 section in an account in the Treasury; and

18 (2) may use the funds in the account, without
 19 further appropriation or fiscal year limitation—

20 (A) to carry out enforcement activities
 21 under food safety law; or

22 (B) to provide assistance to States to in-
 23 spect retail commercial food establishments or
 24 other food or firms under the jurisdiction of
 25 State food safety programs.

1 (f) DISCRETION OF THE ADMINISTRATOR TO PROS-
2 ECUTE.—Nothing in this Act requires the Administrator
3 to report for prosecution, or for the commencement of an
4 action, the violation of the food safety law in a case in
5 which the Administrator finds that the public interest will
6 be adequately served by the assessment of a civil penalty
7 under this section.

8 (g) REMEDIES NOT EXCLUSIVE.—The remedies pro-
9 vided in this section may be in addition to, and not exclu-
10 sive of, other remedies that may be available.

11 **SEC. 406. PRESUMPTION.**

12 In any action to enforce the requirements of the food
13 safety law, the connection with interstate commerce re-
14 quired for jurisdiction shall be presumed to exist.

15 **SEC. 407. WHISTLEBLOWER PROTECTION.**

16 (a) IN GENERAL.—No Federal employee, employee of
17 a Federal contractor or subcontractor, or any individual
18 employed by a company (referred to in this section as a
19 “covered individual”), may be discharged, demoted, sus-
20 pended, threatened, harassed, or in any other manner dis-
21 criminated against, because of any lawful act done by the
22 covered individual to—

23 (1) provide information, cause information to be
24 provided, or otherwise assist in an investigation re-
25 garding any conduct that the covered individual rea-

sonably believes constitutes a violation of any law,
rule, or regulation, or that the covered individual
reasonably believes constitutes a threat to the public
health, when the information or assistance is pro-
vided to, or the investigation is conducted by—

(A) a Federal regulatory or law enforce-
ment agency;

(B) a Member or committee of Congress;
or

(C) a person with supervisory authority
over the covered individual (or such other indi-
vidual who has the authority to investigate, dis-
cover, or terminate misconduct);

(2) file, cause to be filed, testify, participate in,
or otherwise assist in a proceeding or action filed or
about to be filed relating to a violation of any law,
rule, or regulation; or

(3) refused to violate or assist in the violation
of any law, rule, or regulation.

(b) ENFORCEMENT ACTION.—

(1) IN GENERAL.—A covered individual who al-
leges discharge or other discrimination by any per-
son in violation of subsection (a) may seek relief
under subsection (c) by filing a complaint with the
Secretary of Labor. If the Secretary of Labor has

1 not issued a final decision within 180 days after the
2 date on which the complaint is filed and there is no
3 showing that such delay is due to the bad faith of
4 the claimant, the claimant may bring an action at
5 law or equity for de novo review in the appropriate
6 district court of the United States, which shall have
7 jurisdiction over such an action without regard to
8 the amount in controversy.

9 (2) PROCEDURE.—

10 (A) IN GENERAL.—An action under para-
11 graph (1) shall be governed under the rules and
12 procedures set forth in section 42121(b) of title
13 49, United States Code.

14 (B) EXCEPTION.—Notification under sec-
15 tion 42121(b)(1) of title 49, United States
16 Code, shall be made to the person named in the
17 complaint and to the person's employer.

18 (C) BURDENS OF PROOF.—An action
19 brought under paragraph (1) shall be governed
20 by the legal burdens of proof set for in section
21 42121(b) of title 49, United States Code.

22 (D) STATUTE OF LIMITATIONS.—An action
23 under paragraph (1) shall be commenced not
24 later than 90 days after the date on which the
25 violation occurs.

1 (c) REMEDIES.—

2 (1) IN GENERAL.—A covered individual pre-
3 vailing in any action under subsection (b)(1) shall be
4 entitled to all relief necessary to make the covered
5 individual whole.

6 (2) COMPENSATORY DAMAGES.—Relief for any
7 action described in paragraph (1) shall include—

8 (A) reinstatement with the same seniority
9 status that the covered individual would have
10 had, but for the discrimination;

11 (B) the amount of any back pay, with in-
12 terest; and

13 (C) compensation for any special damages
14 sustained as a result of the discrimination, in-
15 cluding litigation costs, expert witness fees, and
16 reasonable attorney's fees.

17 (d) RIGHTS RETAINED BY THE COVERED INDIVIDUAL.—Nothing in this section shall be construed to di-
18 minish the rights, privileges, or remedies of any covered
19 individual under any Federal or State law, or under any
20 collective bargaining agreement.

22 **SEC. 408. ADMINISTRATION AND ENFORCEMENT.**

23 (a) IN GENERAL.—For the efficient administration
24 and enforcement of the food safety law, the provisions (in-
25 cluding provisions relating to penalties) of sections 6, 8,

1 9, and 10 of the Federal Trade Commission Act (15
2 U.S.C. 46, 48, 49, and 50) (except subsections (c) through
3 (h) of section 6 of that Act), relating to the jurisdiction,
4 powers, and duties of the Federal Trade Commission and
5 the Attorney General to administer and enforce that Act,
6 and to the rights and duties of persons with respect to
7 whom the powers are exercised, shall apply to the jurisdic-
8 tion, powers, and duties of the Administrator and the At-
9 torney General in administering and enforcing the provi-
10 sions of the food safety law and to the rights and duties
11 of persons with respect to whom the powers are exercised,
12 respectively.

13 (b) INQUIRIES AND ACTIONS.—

14 (1) IN GENERAL.—The Administrator, in per-
15 son or by such agents as the Administrator may des-
16 ignate, may prosecute any inquiry necessary to carry
17 out the duties of the Administrator under the food
18 safety law in any part of the United States.

19 (2) POWERS.—The powers conferred by sec-
20 tions 9 and 10 of the Federal Trade Commission
21 Act (15 U.S.C. 49 and 50) on the United States dis-
22 trict courts may be exercised for the purposes of this
23 chapter by any United States district court of com-
24 petent jurisdiction.

1 **SEC. 409. CITIZEN CIVIL ACTIONS.**

2 (a) CIVIL ACTIONS.—A person may commence a civil
3 action against—

4 (1) a person that violates a regulation (includ-
5 ing a regulation establishing a performance stand-
6 ard), order, or other action of the Administrator to
7 ensure the safety of food; or

8 (2) the Administrator (in his or her capacity as
9 the Administrator), if the Administrator fails to per-
10 form an act or duty to ensure the safety of food that
11 is not discretionary under the food safety law.

12 (b) COURT.—

13 (1) IN GENERAL.—The action shall be com-
14 menced in the United States district court for the
15 district in which the defendant resides, is found, or
16 has an agent.

17 (2) JURISDICTION.—The court shall have juris-
18 diction, without regard to the amount in con-
19 troversy, or the citizenship of the parties, to enforce
20 a regulation (including a regulation establishing a
21 performance standard), order, or other action of the
22 Administrator, or to order the Administrator to per-
23 form the act or duty.

24 (3) DAMAGES.—The court may—

25 (A) award damages, in the amount of dam-
26 ages actually sustained; and

1 (B) if the court determines it to be in the
 2 interest of justice, award the plaintiff the costs
 3 of suit, including reasonable attorney’s fees,
 4 reasonable expert witness fees, and penalties.

5 (c) REMEDIES NOT EXCLUSIVE.—The remedies pro-
 6 vided for in this section shall be in addition to, and not
 7 exclusive of, other remedies that may be available.

8 **TITLE V—IMPLEMENTATION**

9 **SEC. 501. DEFINITION.**

10 For purposes of this title, the term “transition pe-
 11 riod” means the 12-month period beginning on the effec-
 12 tive date of this Act.

13 **SEC. 502. REORGANIZATION PLAN.**

14 (a) SUBMISSION OF PLAN.—Not later than 180 days
 15 after the effective date of this Act, the President shall
 16 transmit to the appropriate congressional committees a re-
 17 organization plan regarding the following:

18 (1) The transfer of agencies, personnel, assets,
 19 and obligations to the Administration pursuant to
 20 this Act.

21 (2) Any consolidation, reorganization, or
 22 streamlining of agencies transferred to the Adminis-
 23 tration pursuant to this Act.

24 (b) PLAN ELEMENTS.—The plan transmitted under
 25 subsection (a) shall contain, consistent with this Act, such

1 elements as the President determines appropriate, includ-
2 ing the following:

3 (1) Identification of any functions of agencies
4 designated to be transferred to the Administration
5 pursuant to this Act that will not be transferred to
6 the Administration under the plan.

7 (2) Specification of the steps to be taken by the
8 Administrator to organize the Administration, in-
9 cluding the delegation or assignment of functions
10 transferred to the Administration among the officers
11 of the Administration in order to permit the Admin-
12 istration to carry out the functions transferred
13 under the plan.

14 (3) Specification of the funds available to each
15 agency that will be transferred to the Administration
16 as a result of transfers under the plan.

17 (4) Specification of the proposed allocations
18 within the Administration of unexpended funds
19 transferred in connection with transfers under the
20 plan.

21 (5) Specification of any proposed disposition of
22 property, facilities, contracts, records, and other as-
23 sets and obligations of agencies transferred under
24 the plan.

1 (6) Specification of the proposed allocations
2 within the Administration of the functions of the
3 agencies and subdivisions that are not related di-
4 rectly to ensuring the safety of food.

5 (c) MODIFICATION OF PLAN.—The President may,
6 on the basis of consultations with the appropriate congres-
7 sional committees, modify, or revise any part of the plan
8 until that part of the plan becomes effective in accordance
9 with subsection (d).

10 (d) EFFECTIVE DATE.—

11 (1) IN GENERAL.—The reorganization plan de-
12 scribed in this section, including any modifications
13 or revisions of the plan under subsection (c), shall
14 become effective for an agency on the earlier of—

15 (A) the date specified in the plan (or the
16 plan as modified pursuant to subsection (c)),
17 except that such date may not be earlier than
18 90 days after the date the President has trans-
19 mitted the reorganization plan to the appro-
20 priate congressional committees pursuant to
21 subsection (a); or

22 (B) the end of the transition period.

23 (2) STATUTORY CONSTRUCTION.—Nothing in
24 this subsection may be construed to require the
25 transfer of functions, personnel, records, balances of

1 appropriations, or other assets of an agency on a
2 single date.

3 (3) SUPERCEDES EXISTING LAW.—Paragraph
4 (1) shall apply notwithstanding section 905(b) of
5 title 5, United States Code.

6 **SEC. 503. TRANSITIONAL AUTHORITIES.**

7 (a) PROVISION OF ASSISTANCE BY OFFICIALS.—
8 Until the transfer of an agency to the Administration, any
9 official having authority over or function relating to the
10 agency immediately before the effective date of this Act
11 shall provide the Administrator such assistance, including
12 the use of personnel and assets, as the Administrator may
13 request in preparing for the transfer and integration of
14 the agency to the Administration.

15 (b) SERVICES AND PERSONNEL.—During the transi-
16 tion period, upon the request of the Administrator, the
17 head of any executive agency may, on a reimbursable
18 basis, provide services or detail personnel to assist with
19 the transition.

20 (c) ACTING OFFICIALS.—

21 (1) IN GENERAL.—During the transition pe-
22 riod, pending the advice and consent of the Senate
23 to the appointment of an officer required by this Act
24 to be appointed by and with such advice and con-
25 sent, the President may designate any officer whose

1 appointment was required to be made by and with
 2 such advice and consent and who was such an officer
 3 immediately before the effective date of this Act
 4 (and who continues to be in office) or immediately
 5 before such designation, to act in such office until
 6 the same is filled as provided in this Act.

7 (2) COMPENSATION.—While acting pursuant to
 8 paragraph (1), such officers shall receive compensa-
 9 tion at the higher of—

10 (A) the rates provided by this Act for the
 11 respective offices in which they act; or

12 (B) the rates provided for the offices held
 13 at the time of designation.

14 (3) LIMITATION.—Nothing in this Act shall be
 15 construed to require the advice and consent of the
 16 Senate to the appointment by the President to a po-
 17 sition in the Administration of any officer whose
 18 agency is transferred to the Administration pursuant
 19 to this Act and whose duties following such transfer
 20 are germane to those performed before such trans-
 21 fer.

22 (d) TRANSFER OF PERSONNEL, ASSETS, OBLIGA-
 23 TIONS, AND FUNCTION.—

24 (1) IN GENERAL.—Consistent with section 1531
 25 of title 31, United States Code, the personnel, as-

1 sets, liabilities, contracts, property, records, and un-
2 expended balances of appropriations, authorizations,
3 allocations, and other funds that relate to the func-
4 tions transferred under subsection (a) from a Fed-
5 eral agency shall be transferred to the Administra-
6 tion.

7 (2) UNEXPENDED FUNDS.—Unexpended funds
8 transferred under this subsection shall be used by
9 the Administration only for the purposes for which
10 the funds were originally authorized and appro-
11 priated.

12 **SEC. 504. SAVINGS PROVISIONS.**

13 (a) COMPLETED ADMINISTRATIVE ACTIONS.—The
14 enactment of this Act or the transfer of functions under
15 this Act shall not affect any order, determination, rule,
16 regulation, permit, personnel action, agreement, grant,
17 contract, certificate, license, registration, privilege, or
18 other administrative action issued, made, granted, or oth-
19 erwise in effect or final with respect to that agency on
20 the day before the transfer date with respect to the trans-
21 ferred functions

22 (b) PENDING PROCEEDINGS.—Subject to the author-
23 ity of the Administrator under this Act—

24 (1) pending proceedings in an agency, including
25 notices of proposed rulemaking, and applications for

1 licenses, permits, certificates, grants, and financial
2 assistance, shall continue notwithstanding the enact-
3 ment of this Act or the transfer of the agency to the
4 Administration, unless discontinued or modified
5 under the same terms and conditions and to the
6 same extent that such discontinuance could have oc-
7 curred if such enactment or transfer had not oc-
8 curred; and

9 (2) orders issued in such proceedings, and ap-
10 peals therefrom, and payments made pursuant to
11 such orders, shall issue in the same manner on the
12 same terms as if this Act had not been enacted or
13 the agency had not been transferred, and any such
14 order shall continue in effect until amended, modi-
15 fied, superceded, terminated, set aside, or revoked by
16 an officer of the United States or a court of com-
17 petent jurisdiction, or by operation of law.

18 (c) PENDING CIVIL ACTIONS.—Subject to the author-
19 ity of the Administrator under this Act, any civil action
20 commenced with regard to that agency pending before
21 that agency on the day before the transfer date with re-
22 spect to the transferred functions shall continue notwith-
23 standing the enactment of this Act or the transfer of an
24 agency to the Administration.

25 (d) REFERENCES.—

1 (1) IN GENERAL.—After the transfer of func-
2 tions from a Federal agency under this Act, any ref-
3 erence in any other Federal law, Executive order,
4 rule, regulation, directive, document, or other mate-
5 rial to that Federal agency or the head of that agen-
6 cy in connection with the administration or enforce-
7 ment of the food safety laws shall be deemed to be
8 a reference to the Administration or the Adminis-
9 trator, respectively.

10 (2) STATUTORY REPORTING REQUIREMENTS.—
11 Statutory reporting requirements that applied in re-
12 lation to such an agency immediately before the ef-
13 fective date of this Act shall continue to apply fol-
14 lowing such transfer if they refer to the agency by
15 name.

16 **SEC. 505. CONFORMING AMENDMENTS.**

17 (a) EXECUTIVE SCHEDULE.—Section 5313 of title 5,
18 United States Code, is amended by inserting at the end
19 the following new item:
20 “Administrator of Food Safety.”.

21 (b) REPEAL OF CERTAIN PROVISIONS.—Section 18
22 of the Poultry Products Inspection Act (21 U.S.C. 467),
23 section 401 of the Federal Meat Inspection Act (21 U.S.C.
24 671), and section 18 of the Egg Products Inspection Act
25 (21 U.S.C. 1047) are repealed.

1 **SEC. 506. ADDITIONAL TECHNICAL AND CONFORMING**
2 **AMENDMENTS.**

3 Not later than 60 days after the submission of the
4 reorganization plan under section 502, the President shall
5 prepare and submit proposed legislation to Congress con-
6 taining necessary and appropriate technical and con-
7 forming amendments to the Acts listed in section 3(15)
8 of this Act to reflect the changes made by this Act.

9 **SEC. 507. REGULATIONS.**

10 The Administrator may promulgate such regulations
11 as the Administrator determines are necessary or appro-
12 priate to perform the duties of the Administrator.

13 **SEC. 508. AUTHORIZATION OF APPROPRIATIONS.**

14 There are authorized to be appropriated such sums
15 as are necessary to carry out this Act.

16 **SEC. 509. LIMITATION ON AUTHORIZATION OF APPROPRIA-**
17 **TIONS.**

18 For the fiscal year that includes the effective date
19 of this Act, the amount authorized to be appropriated to
20 carry out this Act shall not exceed—

21 (1) the amount appropriated for that fiscal year
22 for the Federal agencies identified in section 102(b)
23 for the purpose of administering or enforcing the
24 food safety law; or

25 (2) the amount appropriated for those agencies
26 for that purpose for the preceding fiscal year, if, as

1 of the effective date of this Act, appropriations for
2 those agencies for the fiscal year that includes the
3 effective date have not yet been made.

4 **SEC. 510. EFFECTIVE DATE.**

5 This Act takes effect on the date of enactment of this
6 Act.

